

REMARKS

Claims 1-7 and 10-34 are pending in this application. Claim 1 has been amended to further clarify the outer and inner end caps. Claims 12, 16 and 20 have been amended to further clarify the present invention and/or correct typographical errors. Dependent claim 35 has been added. No new matter has been added. Reconsideration of the claims in view of the following remarks is respectfully requested.

35 U.S.C. § 103 Rejections

The Office Action has applied two references -- U.S. Patent Application Publication No. 2003/0171696 to Dosmann ("Dosmann") and U.S. Patent Application Publication No. 2003/0018300 to Duchon ("Duchon"). As recognized in the Office Action, Dosmann is missing several limitations of independent claim 1: (a) the claimed lancing mechanism adapted to move between the retracted, lancing and collection positions, (b) the outer end cap and (c) the inner end cap. Page 3 of the Office Action. In an attempt to address these numerous deficiencies, the Office Action has applied Duchon, which is said to disclose the remaining three elements -- the claimed lancing mechanism, the outer end cap and the inner end cap. Pages 3-4 of the Office Action.

Independent Claim 1

Neither Dosmann nor Duchon Discloses A Lancing Mechanism with a Collection Position for Collecting a Body Fluid Sample

As acknowledged in the Office Action, there is no disclosure of a lancing mechanism in Dosmann that is adapted to move between the retracted, lancing and collection positions. Page 3 of the Office Action. Rather, the puncture of a patient's skin in Dosmann is determined by the location of the unmovable lance 12 relative to the housing 18. See par. 10, lines 4-5. The housing 18 of Dosmann controls the depth of a puncture into a patient's skin by the lance 12. Par. 10, lines 4-5. The depth of a puncture corresponds to the length of the lance 12 extending out of the housing 18. Dosmann; Par. 10, 5-7. Thus, the optical format of Dosmann for lancing the skin has a single position. Thus, Dosmann does not disclose, teach or suggest "a lancing mechanism disposed within the body, the lancing mechanism coupled to the lancet at an end of the lancet opposite the tip, the lancing mechanism being adapted to move the lancet between a

retracted position, a lancing position for puncturing the skin of a test subject, and a collection position for collecting the body fluid sample” as recited in claim 1.

Duchon appears to disclose retracted and lancing positions, but not a collection position. FIGs. 13A-13I of Duchon show a sequence of a lancing operation, but a collection position is not disclosed with respect to lancet 53. The lack of a collection position is also apparent from the disclosure involving the last operational step (FIG. 13I):

When the forward force on the sleeve 12 is released (FIG. 13I) the sleeve is retracted by the sleeve spring 126, causing the force applied by the inner ring 22 against the skin to be relieved. According, the sides of the incision I close, and fresh fluid (previously blocked by the depressed skin and body tissue) flows toward the incision to replace the fluid which had been forced from the incision. As the forward force is reapplied to the sleeve and thus to the inner ring (see FIG. 13H), the above-described action is repeated, and additional fluid is forced upwardly through the incision. Eventually, this “pumping” action results in the formation of a suitably large drop B of body fluid capable of being sampled.

Paragraph 68 of Duchon. Thus, Duchon also does not disclose, teach or suggest the claimed lancing mechanism with a collection position as recited in claim 1.

Neither Dosmann nor Duchon Discloses the Claimed Outer and Inner End Caps.

Amended claim 1 recites (1) “an outer end cap having a first end coupled to the open end of the body and a second end for contacting the skin of the test subject, the outer end cap forming a first aperture therein that the tip of the lancet enters when in the lancing position, the outer end cap having a wall extending to the second end thereof,” and (2) “an inner end cap disposed within the outer end cap, the inner end cap having a first end coupled to the open end of the body and a second end forming a second aperture therein that the tip of the lancet enters when in the lancing position, the second end being adapted to contact the skin of the test subject when the lancet is in the collecting position, the inner end cap having a wall extending to the second end thereof, the wall of the outer end cap extending farther towards the skin than the wall of the inner end cap during lancing such that the skin of the test subject is drawn inside of the outer end cap and contacts the inner end cap.”

As acknowledged in the Office Action, Dosmann does not disclose inner and outer end caps. Page 3. The Office Action also states that Duchon discloses “[t]he outer end cap has a first end coupled to the open end of the body (element 12) and the second end of the outer cap

for contacting the skin (figure 13f). The second end of the inner cap also contacts the skin when the lancet is in the collecting position (figures 13h and 13i).” Page 4 of the Office Action. Amended claim 1 recites “the inner end cap having a wall extending to an open end therefrom, the wall of the outer end cap extending farther than the wall of the inner end cap during lancing such that the skin of the test subject is drawn inside of the outer end cap and contacts the inner end cap.” On the other hand, the inner portion of Duchon extends further than its outer portion during lancing in which the skin of the test subject is not drawn within the outer portion. See, e.g., FIG. 13G of Duchon. The claimed inner and outer end cap is advantageous as explained in the present invention because the outer end cap contacts a test subject’s skin and the test subject’s skin is pulled against the inner end cap during the lancing operation. See page 3, lines 23-29 of the patent application. Thus, the test subject’s skin is stretched flat against the open end of the inner end cap and “[t]his stretched, flat skin facilitates sample formation and collection.” See page 6, lines 20-22 of the patent application.

Thus, neither Duchon nor Dosmann discloses, teaches or suggests the claimed outer and inner end caps as recited in claim 1.

There is No Teaching or Suggestion to a Skilled Person to Combine Dosmann and Duchon for Several Reasons.

First, the lancing mechanism of Duchon is quite different from that of Dosmann. As discussed above, the lance of Dosmann is unmovable and, thus, has a single position. See par. 10, lines 4-5 of Dosmann; FIG. 1. The housing 18 of Dosmann controls the depth of a puncture into a patient’s skin by the lance 12. Par. 10, lines 4-5. The depth of a puncture corresponds to the length of the lance 12 extending out of the housing 18. Dosmann; Par. 10, 5-7. Duchon, on the other hand, is movable and is adapted to move between retracted and lancing positions as discussed above. See also generally paragraphs 64-68 of Duchon describing the use of the sampler.

Second, Dosmann discloses that it is a disposable optical format/integrated lance for lancing the skin. See abstract of Dosmann. Duchon does not disclose a disposable lancing device, but rather only discloses a disposable lancet member 15 that is carried by a lancet tip assembly 16. Page 3, Par. 42; FIG. 2 of Duchon. The lancing device disclosed in Duchon is reusable after the disposable lancet member 15 has been replaced. Thus, the devices disclosed in

Dosmann and Duchon have different uses – the lance of Dosmann is disposable, while the lancing device of Duchon is reusable.

Third, Dosmann is directed to an optical format that is integrated with a lancing device such that an analyte concentration is determined using an optical technique. See, e.g., Par. 11 of Dosmann; paragraph 4 (describing the process of lancing and continuing through the optical analysis of the sample). Duchon, on the other hand, does not disclose, teach or suggest the use of an integrated device for determining an analyte concentration, let alone determining an analyte concentration using an optical technique. Rather, Duchon is simply a lancing device.

Thus, in summary, a skilled person would not look to combine the disposable unretracted integrated lance with optical format of Dosmann with the relatively complex lancing mechanism of Duchon that is not capable of determining an analyte concentration.

Therefore, claim 1 is not obvious over Dosmann, Duchon or the combination thereof and, thus, claim 1 should be allowable.

Dependent Claims 1-11 and 35

For at least the same reasons as discussed above with respect to independent claim 1, the dependents claims also have an inventive step over Dosmann, Duchon or the combination thereof. Additionally, the dependent claims have additional reasons that they should be allowable over Dosmann, Duchon or the combination thereof.

For example, amended claim 35 now recites “wherein the inner end cap remains entirely disposed within the outer end cap during the retracted position, the lancing position and the collection position”. As discussed above, Dosmann does not even disclose an inner or outer cap, let alone a lance that is movable between multiple positions. Thus, Dosmann does not disclose, teach or suggest the limitations of claim 35. In addition to not disclosing, teaching or suggesting having a lancing mechanism in the collection position, Duchon does not disclose the recited embodiment wherein the inner end cap remains entirely disposed within the outer end cap. Specifically, during the lancing operation of Duchon, an inner ring 22 is located within the outer ring 24 in the retracted position (see FIG. 13A), but in the lancing position, the inner ring extends beyond the outer ring 24 (see FIG. 13H). Compare, for example, FIG. 13H of Duchon with FIGs. 2-4 of the present invention. Thus, Duchon does not disclose, teach or suggest the limitations of claim 35.

Claim 11 recites “wherein the retracted position and the collection position are substantially the same.” As discussed above with respect to independent claim 1, neither Dosmann nor Duchon has the claimed collection position, let alone having a collection position being substantially the same as the retracted position as recited in claim 11. Thus, Dosmann, Duchon or the combination thereof does not disclose, teach or suggest the limitations of claim 11.

Independent Claim 12

Amended claim 12 recites “puncturing the skin with the lancet by moving from a retracted position to a lancing position” and “collecting the body fluid sample from the puncture skin with the tip of the lancet in a collection position.” Claim 12 also recites an outer end cap and inner end cap of the device in separate acts. As discussed above with respect to claim 1, Dosmann does not *inter alia*, disclose a lancing mechanism that includes a retracted position, a lancing position and a collection position. For the same reasons as discussed above in claim 1, Duchon does not disclose, teach or suggest a lancing mechanism that includes a retracted position, a lancing position and a collection position and, thus, this deficiency of Dosmann has not been addressed. Additionally, there is no teaching or suggestion to a skilled person to combine Dosmann and Duchon for the reasons discussed above in claim 1.

Therefore, claim 12 is not obvious over Dosmann, Duchon or the combination thereof and, thus, claim 12 should be allowable.

Dependent Claims 13-19

For at least the same reasons as discussed above with respect to independent claim 12, the dependents claims 13-19 also are not obvious over Dosmann, Duchon or the combination thereof. Therefore, claim 13-19 should also be in a condition for allowance.

Independent Claim 20

Claim 20 recites a lancet that is adapted to move between a retracted position, a lancing position and a collection position. As discussed above with respect to claim 1, Dosmann does not disclose a lancet that moves between a retracted position, a lancing position and a collection position. For the same reasons as discussed above in claim 1, Duchon does not teach a lancet that moves between a retracted position, a lancing position and a collection position and, thus, this deficiency of Dosmann has not been addressed. Additionally, there is no teaching or suggestion to a skilled person to combine Dosmann and Duchon for the reasons discussed above in claim 1.

Therefore, claim 20 is not obvious Dosmann, Duchon or the combination thereof and, thus, claim 20 should be allowable.

Dependent Claims 21-34

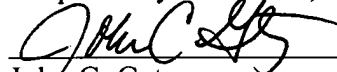
- For at least the same reasons as discussed above with respect to independent claim 20, the dependents claims 21-34 also are not obvious over Dosmann, Duchon or the combination thereof. Therefore, claim 21-34 should also be in a condition for allowance.

CONCLUSION

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. It is believed that no fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Nixon Peabody LLP Deposit Account No. 50-4181, Order No. 247082-000090USPX.

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